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September 28, 1999

Dockets Management Branch - HFA 305
FDA
5630 Fishers Lane - Room 1061
Rockville, MD 20852

Re: Docket No. 99D-2152

Medical Devices; Device Use Safety: Incorporating Human Factors in Risk Management; Availability

Dear Management Branch:

I am commenting to the proposed guidance.

In 1991, while working as a licensed x-ray technologist in a large municipal hospital as a mammographer, I became alarmed that my mammography equipment could not be disinfected according to the disinfectant manufacturer's instruction for the following reasons:

Some mammography device manufacturers warned about getting any liquids into the bucky because of **electrical safety**. Others warned to shut the circuit breaker before attempting to use any chemical on the equipment. Chemical disinfectants such as "alcohol" was not recommended because it "pitted" the plastic used in the compression paddle and bucky, and is combustible.

When searching for an appropriate disinfectant I realized that they posed many problems. For instance, on many bucky's there were metal screws on the surface, the bucky had a metal interior in the housing. Bleach, which is a disinfectant, would "**rust**" these parts.

There were other considerations I looked at when selecting a disinfectant, and that included "**allergic reactions**" to patients and technologists. Bleach, a common disinfectant cautioned people with "asthma" not to use. Then there was skin contact allergic reaction. For instance, one device manufacturer recommended a chemical that was meant for "**immersion only**."

The medical device manufacturer recommended "wiping the surface" with this chemical. When I contacted J & J the chemical manufacturer, they said if the technologist wiped the surface that the patient would get a "chemical burn" and was not meant for this use. Other chemicals risked chemical build up, because rinsing was not possible for the bucky. **Ventilation, protective clothing, immersion time, special containers should be considered when selecting a disinfectant.**

Mammography equipment has **direct skin contact** with the patient. The surfaces sometimes become **contaminated with nipple discharge, and blood**. Patients frequently "**shave the underarms**." Lateral positioning requires underarm position on the equipment. This **freshly shaven skin** can serve as a "**host**" for **bloodborne pathogens cross contamination**.

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Technologists who bite their nails and cuticles can come into contact with bloodborne pathogens from nipple discharge during positioning if they do not wear gloves. These skin nic, can serve as a host if exposed to bloodborne pathogens. Some patients without breast disease have **"spontaneous nipple discharge"** during the compression and is considered bloodborne pathogens. It is impossible to determine who will have this.

If a technologist does wear latex gloves, they may contain **"powder"** which can create **artifacts** on the mammography films. Equipment parts made of plastic are not labeled **"which plastic is used."** Chemicals react differently on different plastics. Polyethylene can use one chemical and not another. The same is true on polycarbonate, etc. There is no way to determine which plastic is used by site. I would recommend labeling the parts what they are made of.

All **"high level disinfectants"** that is necessary when a surface becomes contaminated with bloodborne pathogens (nipple discharge, blood) requires approximately 45 minutes **"immersion time"** and **"rinsing with sterile water."** The compression paddles can accomplish this. However, the bucky is **not constructed the be "immersed."** Rinsing the bucky is not possible.

There is no way to determine if the bucky housing is wet or dry. The bucky houses electrical components, and if wet can pose a threat of electrical shock. Combustion is also possible when using certain chemicals, i.e. alcohol, and electrical equipment.

If barriers are used, they must be FDA approved because the radiation dose may be affected and distortion can occur. Plastics react differently with radiation. Some plastics will **distort images**, and require **more radiation to the patient**. Thermoformed plastics must have smooth services, because the patient leans into the equipment. Sharp flanges could cut a patient and hurt them.

What I determined was that **"non attenuating, plastic, disposable barriers"** was the best choice. I have a patent and offered all of the medical device manufacturers a license. Each medical device manufacturer would have to **"custom thermoform"** the barrier to their particular model, because there is not a generic design.

Thermoforming is desirable, because the barrier should fit flush with the equipment surface. If the breast is not flush to the equipment, the film will **show distortion** and may not pick up breast details and even miss cancers. None of the medical device manufacturers offer a barrier for the bucky or compression paddles.

Cleaning and disinfecting instructions are inadequate, or blatantly wrong. One manufacturer even recommends **"car polish"** for cleaning and disinfecting. The ultimate outcome is that it is **not possible to properly disinfect and clean the bucky because of its construction and design.** Women are exposed to body fluid contaminates from previous patients, and women with freshly shaven under arms are put at risk for potential cross contamination.

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The FDA and medical device manufacturers know of this potential for cross contamination, know that there is no way to chemically disinfect the bucky, and allows 25 million women potentially to be exposed to bloodborne pathogens.

This is wrong, this is bad medicine, and I believe that the patient should be "warned of their potential risk of exposure." The patients however are never told of this. Bloodborne pathogens will live in a dried state for more than two weeks, if not properly disinfected.

Under Hazards Related to Device Use, I would include "Distortion Hazards," "Chemical Contact Hazards," "Chemical Cleaning and Disinfectant Hazards," "Barrier Hazards" and "Patient and User Hazards"

I would also recommend that the device manufacturer label each part with materials that were used for manufacturing each part. Any "chemicals used for cleaning and disinfection should be tested by device manufacturer under "Reuse."

I believe that the medical device manufacturer should post a **visible health warning** to patients for potential health hazards that cannot be eliminated.

Thank you.

Sincerely,

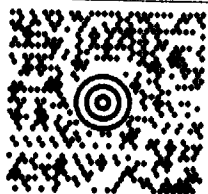
A handwritten signature in black ink, appearing to read "Eleanor Sherman", written in a cursive style.

Eleanor Sherman

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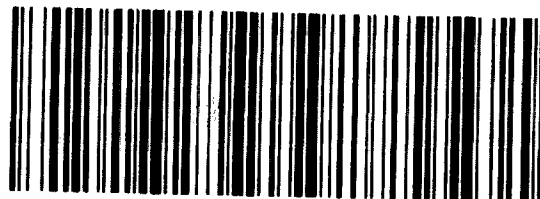


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